SCOPE Biphasic

Data-Pak Battery

Atrial Defribillation

Heartsine Research

Patents

Learning More About SCOPE™ Biphasic

The clinical rationale and advantages of low-energy biphasic defibrillation have been clearly demonstrated. Heartsine has developed a unique, patented (pending) biphasic defibrillation energy delivering system, which provides an advanced technology platform for our family of AED devices.

Until the recent introduction and uses of biphasic waveforms for providing external defibrillation therapy, the technology for defibrillation energy delivery has remained unchanged. Traditionally over the past 30 years or more defibrillation energy delivery was provided by one of several types of monophasic waveforms.

To be effective monophasic waveforms must provide much higher energy delivery than the newer biphasic technology. The development of the biphasic waveform was actually driven by the needs of the implantable defibrillator market since some of the components used to produce the standard monophasic waveforms were not applicable for implant circuitry. A number of studies have shown biphasic waveforms to have equal or superior efficacy to traditional monophasic waveforms while reducing total energy required for successful defibrillation in both implantable and external defibrillators. This has been observed for both in-hospital and out-of-hospital cardiac arrests. Use of the biphasic waveform has become the standard for implantable defibrillator devices and is now being used on external devices as well.

While biphasic waveforms have shown to be efficacious when used in Public Access Programs using Automated External Defibrillators, it should be noted that all biphasic waveforms are not alike. Biphasic waveforms perform differently based on their capacitors and impedance compensating circuits.

Our partners at the University of Ulster's, Northern Ireland Bioengineering Centre and the Royal Victoria Hospital have a long history of advanced research in the field of cardiovascular medicine and specifically cardiac defibrillation. In recent years an aspect of their research activity has focused on developing unique technologies for implantable defibrillation including the optimisation of the biphasic waveform. Their work investigated a variety of biphasic and triphasic waveforms at different pulse widths and amplitudes in animal models

Interactive Demos

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of Ventricular Fibrillation (VF). Detailed studies focused on determining the best shape for the biphasic waveform and current work indicates that between 3 and 6 ms per phase appears optimal for external biphasic defibrillation. It has been determined that 40-50% less energy can be used to effect conversion with the appropriate biphasic waveform when compared against the damped sinusoidal waveforms.

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HeartSine's internal engineering team utilized various aspects of this research as the foundation for the development of an optimised biphasic waveform, SCOPE™, for use in its SAMARITAN™ family of Automated External Defibrillators (AEDs). This project focused on optimising the biphasic energy delivery waveform through the integration of variable energy, slope and envelope with patient impedance to produce what we believe to be the most effective vehicle available for providing effective low-energy ventricular defibrillation over the widest range of patients. Optimising electrical energy delivery will provide more efficient defibrillation and hopefully allow smaller and less expensive defibrillators to be marketed.

The SAMARITAN® AED also has an embedded, proprietary arrhythmia detection algorithm for effectively recognizing shockable cardiac rhythms. This algorithm, which has been in use for a number of years was recently redesigned by our engineering team.

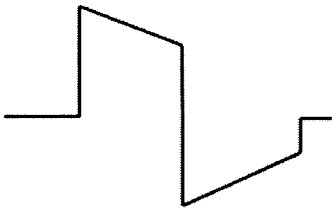
SCOPE™ (Self Compensating Output Pulse Envelope) Biphasic Energy Delivery Waveform

Any new approach utilising biphasic technology must compensate for patient impedance whilst at the same time provide the optimal pulse width for a broad range of patient impedance.

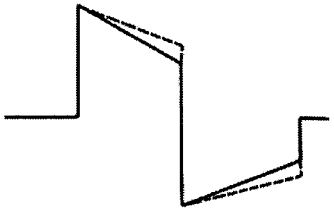
Additionally the discharge characteristics must be modified to provide an appropriate current envelope for this broad range The SCOPE waveform will therefore compensate for:

1) Current profile.
2) Amplitude changes to ensure the correct selected energy to variable impedance source.
3) Function within a set of pulse widths to provide the optimal phase structure for effective defibrillation.

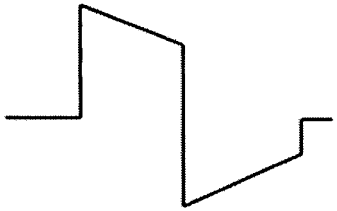
1. Current Profile



Low impedance patients create a faster discharge rate i.e. a steeper slope for the phased duration.

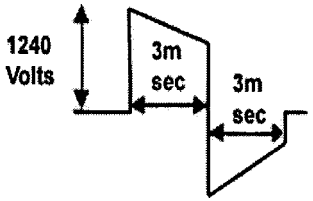


SCOPE compensates for this effect by switching in capacitance changes to provide an optimal current profile. Low impedance i.e. the dotted line shows the compensation effect of capacitance switching.

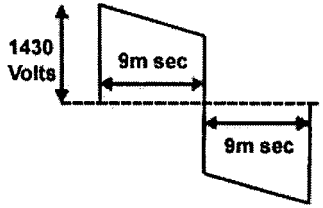


High impedance patients have a slope again similar to that achieved for low impedance patients by the effect of switching capacitance.

2. Amplitude Changes

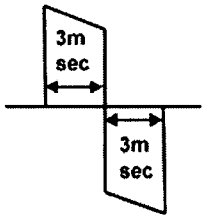


SCOPE will vary the amplitude and pulse width of the waveform to compensate for a broad range of patient impedances. Such an approach also compensates for the current delivered to low impedance patients. For example at 1240 volts and 3 ms 100J will be delivered to a patient impedance ranging from 20-30 ohms.

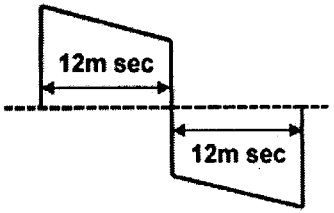


At patient impedances as high as 170-180 ohms 100J will again be delivered by SCOPEô automatically adjusting the amplitude and pulse width of the envelope.

3. Pulse Width Management



Research indicates the efficacy of biphasic waveforms is significantly reduced at pulse widths beyond 16 ms. By compensating for amplitude over a large impedance range, SCOPE can deliver the major portion of its energy pulse between 3-12 ms This compensation provides for a range of impedances from 50-120 ohms.



4. Additional Safety Factors

Additionally SCOPE will limit the current delivered at higher energies e.g. 200J will not be delivered to impedances less than 20 ohms and 230J cannot be delivered for impedances less than 30 ohms.

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